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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,853

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Ryo Takeshita

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10/03/2006

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/791,853

Applicant(s)

TAKESHITA ET AL.

Examiner

Irene Marx

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the antecedent basis for "the alkane" is unclear. Is it the alkane not inherently utilized or the alkane that is oxidized into an alcohol? Also, the phrase "and an alcohol which is general by oxidation of an alkane" appears redundant. The antecedent basis for "the obtained culture" is unclear and the recitation of "allowing... to exist with" renders the claim indefinite. Terminology such as "contacting" is recommended.

Claims 1 is vague, indefinite and confusing in that it is unclear whether the same or different alcohols are present in the process. This issue is raised by the second "wherein" recitations of claim 8.

Claim 1 is confusing in that the intended meaning of "processed product of said cells" is not clearly delineated.

Claim 4 is vague and indefinite and appears contradictory and incorrect in the recitation "soluble-type methane oxygenase gene", since more than one gene appears to be involved. See, e.g., claim 3.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *E. coli* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 12 that the strain was deposited at National Institute of Biosciences and Human Technology of the Agency of Industrial Science and Technology under Budapest Treaty conditions on 8/19/02.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Higgins *et al.* (U.S. Patent No. 4,318,784).

The claims are directed to a method of making an alcohol with a processed product obtained from a cell, wherein the cell is a recombinant microorganism which does not inherently use an alkane.

Higgins *et al.* disclose the biotransformation of methane to methanol using a crude cell-free extract obtained from *M. trichosporium*. Even though the source of the extract is not a recombinant microorganism which does not inherently use an alkane, the nature of the enzymatically active extract is deemed to be the same, since the same proteins are involved in the bioconversion.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by

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evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, the claims are deemed to be anticipated by the reference.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Colby *et al.*

The claims are directed to a method of making an alcohol with a processed product obtained from a cell, wherein the cell is a recombinant microorganism which does not inherently use an alkane.

Colby *et al.* disclose the biotransformation of methane to methanol using a cell-free extract obtained from *M. capsulatus*. Even though the source of the extract is not a recombinant microorganism which does not inherently use an alkane, the nature of the enzymatically active extract is deemed to be the same, since the same proteins are involved in the bioconversion.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially

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identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, the claims are deemed to be anticipated by the reference.

Claims 1, 2, 3, 7, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lloyd *et al.* (Microbiology (1999), vol. 145, pages 461-470)

The claims are directed to a method of making an alcohol with a recombinant microorganism which does not inherently use an alkane.

Lloyd *et al.* teach a method of culturing mutant strains of *M. trichosporium* which have lost the ability to inherently use an alkane (page 466, paragraph 1) and which have been transformed with soluble methane monooxygenase genes such that the recombinant microorganisms become capable of using an alkane such as methane (page 465, last paragraph). That the transformed microorganisms make at least some methanol can be presumed from the disclosure at page 461, from which it is clear that at least some of the methane used is biotransformed to produce at least some methanol.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lloyd *et al.* taken with Stainthorpe *et al.* and West *et al.*

Lloyd *et al.*, disclose the bioconversion of methane to methanol with *M. trichosporium* (See, e.g., page 461, paragraph 1) and also disclose that the genes encoding for soluble methane mono-oxygenase have been cloned and sequenced. See, e.g., page 462, paragraph 4. In addition, the reference teaches a method of culturing mutant strains of *M. trichosporium* which have lost the ability to inherently use an alkane (page 466, paragraph 1) and which have been transformed with soluble methane monooxygenase genes such that the recombinant microorganisms become capable of using an alkane such as methane (page 465, last paragraph). That the transformed microorganisms make at least some methanol can be presumed from the

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disclosure at page 461, from which it is clear that at least some of the methane used is biotransformed to produce at least some methanol.

The reference differs from the invention as claimed in that it does not disclose the production of an alcohol such as methanol wherein the transformed microorganism is *Escherichia*, for example. However, West *et al.* disclose the transformation of *E. coli* with methane monooxygenase genes, that are expressed. In addition, Stainthorpe *et al.* discusses the genetic composition of the mono-oxygenase from *Methylococcus capsulatus*.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in transforming *Escherichia* or other suitable microorganisms with the genes obtained from strains of a *Methylococcus capsulatus* strain, for example, for the production of an alcohol from an alkane.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Lloyd *et al.* by using a transformed strain of *Escherichia* as taught by West *et al.* for the expected benefits of reducing the concentrations of atmospheric methane by producing methanol from methane in an economic and efficient manner.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Irene Marx*  
Irene Marx

Primary Examiner